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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

LIN, JEYUHU

ART UNIT PAPER NUMBER

3737

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

EC

Office Action Summary

Application No.

09/872,310

Applicant(s)

AINSWORTH ET AL.

Examiner

Jeoyuh Lin

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-39 is/are allowed.
- 6) ☒ Claim(s) 1-29 and 31-35 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

-Claims 1-20, 22-28, and 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Vander Salm et al. (US 5,906,579)

Vander Salm teaches a through-wall catheter steering and position device, comprising the following structures:

- A catheter with outer member disposed about a tubular inner member, with an intraluminal gap (Figure 3)
- Inflatable balloon to occlude bloodflow and secure the position of the catheter, (Column 6, lines 1-13) as in claim 16.
- Lumen, as in claim 17, that could deliver therapeutic drugs, as claim 18 claims.
- Optic fiber with light source in contact with the vasculature to mark the location of the balloon (Figure 3), with the possibility of using a separate endoscope to

capture an image of the area. (Column 6, lines 26-67, column 7, lines 1-21, column 11, lines 48-55 and column 13, lines 65-67 and column 14, lines 1-10)

-Measuring of hematological parameters, such as blood pressure, through a monitor lumen, as claim 20 teaches. (Column 11, lines 56-67)

-Data processing system. (Column 6, line 40, item 46)

While Vander Salm fails to teach optic fiber in the monitor lumen it is well known in the art of diagnostics that optic fiber may be used to monitor various vascular parameters.

-Claims 1, 2, 15, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Daniel et al. (US 6,258,083).

Daniel teaches a transmyocardial revascularization imager comprising the following structures:

-A laser therapeutic laser fiber, (Column 7, lines 25-48) that is steerable within the catheter with the possibility of combining it with other therapeutic devices. (Column 15, lines 44-63).

-Endoscope including a fiber providing diagnostic information in the form of an image, which is exposed to the vasculature. (Column 8, line 10) and optic fiber that delivers therapeutic laser and is coupled with other therapeutic devices. (Column 7, lines 25-48 and column 15, lines 44-63)

Daniel fails to teach a balloon.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

-Claims 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vander Salm et al. as applied to claim 1 above, and further in view of Hillsman et al. (US 5,514,218).

Vander Salm meets all the claims except that it fails to teach an optic fiber comprising radiopaque substance. Hillsman teaches a fiber optic wire guide catheter with a radiopaque coil. (Column 8, lines 50-67) It would have been obvious to one having ordinary skill in the art at the time the invention was made to adapt Hillsman's teachings into Vander Salm's device in order to track the position of the catheter in the patient more accurately.

Allowable Subject Matter

3. Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
4. Claims 36-39 are allowable.

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

-Lamelson (US 6,400,980) teaches an intravascular device comprising a fiber optic imager that provides diagnostic information throughout the therapeutic procedure (Column 22, lines 5-51)

-Duhaylongsod et al. Duhaylongsod et al. teaches a fiber optic transillumination device that illuminates the blood vessel during a surgical procedure (Paragraph 28) with a balloon to hold the illuminator in place. (Paragraph 30 and 45)

However, no diagnosis is performed,

-Fiddian-Green (US 5,456,251 and US 6,238,339 B1) teaches a tonometric catheter comprising fiber optic providing diagnostic information such as a fluid pH or gas property, as well as a plurality of sensors. However, it fails to teach its use in conjunction with a therapeutic device. Also, the device is adapted for use in the gastrointestinal or urinary system, not intravascular.

-Hillsman et al. (US 5,514,128) teaches a fiber optic guide and support, comprising a fiber optic guide wire, with detailed catheter structure description, and with the ability to adapt the device for use in conjunction with a therapeutic device.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeoyuh Lin whose telephone number is (703) 306-5990. The examiner can normally be reached on m-f, 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marvin Lateef can be reached on (703) 308-3256. The fax phone numbers


Art Unit: 3737

for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

JYL

JYL
May 29, 2003


Marvin M. Lateef
Supervisory Patent Examiner
Group 3700